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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Russell A. Houser
Serial No. : 09/632,519
Filed : August 4, 2000
Title : Percutaneous Transluminal Myocardial Revascularization (PTMR) System
Art Unit : 3763
Examiner : Manuel Mendez

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO OFFICE ACTION DATED DECEMBER 23, 2003

In view of the following remarks, reconsideration and allowance of this application are requested. Claims 1-29 are pending with claims 9, 15, 21, and 22 being withdrawn from consideration. Claims 1, 10, 19, and 26 are independent.

Claims 1, 10, 19, and 26 have been rejected as being obvious over Parins (U.S. Patent No. 4,976,711) in view of Okada et al. (U.S. Patent No. 3,910,279) and/or Tihon et al. (U.S. Patent No. 5,415,656). Claim 1 is directed to a device for performing percutaneous transmyocardial revascularization and includes an elongate catheter, a cutting element, and a control component. The elongate catheter has a proximal end and a distal end, a catheter wall defining a compartment within the catheter, and at least one window through the catheter wall open to the compartment. The cutting element is compressible into a reduced diameter when positioned within the compartment and tends to radially expand beyond the catheter wall when positioned near the at least one window. The control component is coupled to the cutting element and operable to selectively position and move the cutting element to a location near the window to allow the radial expansion through the window.

Parins is directed to an ablation catheter with deployable electrodes that are adjacent a window. See Figs. 2, 4 and 5 and col. 4, lines 29-38. Parins describes an important aspect of the invention as being the ability to route the catheter through the vascular system with the catheter having a low cross-sectional profile and then, upon reaching the site for ablation, increasing its cross-sectional profile to contact the electrodes against tissue to be ablated. See col. 3, lines 39-48. Parins describes one means of contacting the electrodes against the tissue as inflating a balloon 40. However, as recognized in the Office Action, Parins does not teach the use of a cutting element compressible into a reduced diameter when positioned within the compartment and tending to radially expand beyond the catheter wall when positioned near the window.

Although the Office Action relies on Okada and Tihon to supply this missing element, Applicant respectfully submits that neither Okada nor Tihon supply this missing element.

Okada et al. is directed to an insulating tube 1 that includes a distal end that has an opening 2 through the side of the tube. A distal end 5 of a wire 3 is fixed at the distal end of the insulating tube and can be projected out of the opening 2 to form a loop 6 to cut tissue. See Figs. 4-6. Okada et al. states that the wire 3 can be pushed into the tube such that the loop 6 is formed. See col. 3, lines 59-67. The wire 3 appears to correspond most closely to the cutting element of claim 1. However, the wire 3 of Okada et al. is not compressible into a reduced diameter nor does it tend to radially expand beyond the catheter wall, as recited in claim 1. Instead, as stated by Okada, the wire must be pushed to form the loop:

> "When, as later described, the wire 3 is pushed toward the forward end portion 1a along the axial line of the tube 1 as indicated by an arrow of FIG. 1, it is made to round out in the form of a large loop transversely to the axial line of the tube 1 as denoted by two dots-and-dash lines of Fig. 1. . . . . In other words, upon pushing-into operation of the wire 3 the working section 6 is outwardly looped in a manner going away from the outer circumference of the tube 1 along the axial line thereof[.]"
>
> See col. 3, lines 53-66.
>
> "[T]he condition in which the wires 3 and 30 are forced into the tube 1 to permit both working sections 6 and 60 to be largely looped exteriorly of the tube 1 is shown."
>
> See col. 7, lines 10-15.

Okada also shows that the operator causes or forces the wire to radially expand beyond the catheter wall (i.e., the wire does not have the tendency to expand beyond the catheter wall), rather than the cutting element tending to radially expand beyond the catheter wall, as recited in claim 1:

> "{T]he pushing-into or drawing-out operation by an operator of the wire 3 is carried out along the axial line of the tube 1[.]"
>
> See col. 3, line 67 through col. 4, line 2.
>
> "Namely, the operator moves the knob member 11 in a direction in which it approaches the grip member 9, with the grip member 9 held by the fingers of one hand and the knob member 11 held by the fingers of another. Then, the wire 3 is forced into the tube 1 to permit the working section 6 to be outwardly looped as indicated by two dots-and-dash lines of Fig. 1. On the other hand, if the operator

> moves the knob member 11 in a direction in which it goes away from the grip member 9, the wire 3 will be drawn out from the tube 1, so that the working section 6 is returned to the shrunk state[.]"
>
> See col. 5, lines 51-63.
>
> "When the body section 400 is pushed in an arrow-indicated direction by the manual operation of the operator, the both working sections 6 and 60 are projectively looped exteriorly of the tube 1. On the other hand, when the body section 400 is pulled in the opposite direction, the two looped working sections 6 and 60 are shrunk at the same time."
>
> See col. 7, lines 55-62.

Similarly, contrary to the Office Action, Tihon does not teach the use of a cutting element compressible into a reduced diameter when positioned within the compartment and tending to radially expand beyond the catheter wall when positioned near the window. As described below, instead of tending to radially expand Tihon teaches pulling a wire to deflect a portion of the wire out of a slot and form a loop.

The Office Action refers to Figures 1 and 2 of Tihon for disclosing the element missing from Parins. As described at Col. 5, lines 9-38, these figures disclose an apparatus that includes a sheath 6 that includes a pair of limbs 3 and 4 through which "a deflectable electrically conducting wire 1" passes. The wire has an electrically insulating coating or sheath 5 along a portion of its length. Tihon states that of the wire, "only the potion to be deflected and form the cutting element is exposed." See Col. 5, lines 13-16. The distal end of the wire is pulled to deflect the exposed proximal portion of the wire outwardly in a direction transverse to the longitudinal axis while holding the limb 3 fixed. In so doing, a loop of wire is bowed outwardly (i.e., forced out of the window). As disclosed by Tihon, this wire is always adjacent to a slot or window in the proximal end of the sheath 6 but it expands radially through the window only by using force to pull back the wire.

Applicant submits that Figures 1 and 2 of Tihon, and the accompanying description, do not teach the wire tending to expand beyond the window but instead teach forcing the wire beyond the window. For example, Tihon states that the wire may be made of a superelastic alloy and "the deflected position is attained by deflecting the wire loop outwardly in a direction transverse to the longitudinal axis of the apparatus, and the apparatus may be include means for controlling the degree of deflection of the wire loop." See Col. 3, lines 2-9. Although Tihon

refers to the use of a superelastic alloy, Tihon does not indicate that the wire has a shape such that it tends to expand radially through the window. To the contrary, the wire is deflected radially through the window by the operator exerting a force, namely, pulling back the wire. In so doing, the distance between the proximal ends of the insulated lengths of the wire is shortened such that the exposed wire portion can only be deflected outwardly.

Applicant notes that Tihon discloses two embodiments of electrodes that are described as bending upwardly when "advanced out of the tube." See Col. 4, lines 17-26. However, these two embodiments do not refer to positioning the electrodes adjacent to a window such that the electrode can expand radially through the window. Instead, Tihon describes advancing them out of the tube (i.e., the end of the tube), which eliminates the constraining force of the tube and allows the previously restrained electrode to bend upwardly.

For at least these reasons, claim 1 is allowable over Parins in view of Okada and Tihon taken separately or in combination.

Claim 10 is directed to an elongate catheter for cutting incisions into heart tissue. The catheter includes at least one window, at least one support strand, a cutting element, and a first control component. The at least one window through the catheter wall is adapted to be positioned against a first tissue surface such that the at least one window faces the first tissue surface. The at least one support strand is adapted to be manipulated into contact with a second tissue surface separate from the first tissue surface to force the at least one window into contact with the first tissue surface. The cutting element has a tendency to expand beyond the catheter wall when positioned near the at least one window to contact the first tissue surface when positioned near the at least one window such that the cutting element cuts tissue adjacent the at least one window to a predetermined depth determined by the shape of the cutting element. The first control component is coupled to the cutting element and operable to selectively position and move the cutting element along the at least one window.

Claim 10, like claim 1, recites a cutting element having a tendency to expand beyond the catheter wall when positioned near the at least one window. As such, claim 10 is allowable over Parins in view of Okada and Tihon for the same reasons that claim 1 is allowable over Parins in view of Okada and Tihon taken separately or in combination.

Claim 19, like claim 10, recites a catheter in which the cutting element has a tendency to expand beyond the catheter wall. Accordingly, claim 19 is allowable over Parins in view of Okada and Tihon, taken separately or in combination.

Claim 26, like claim 10, recites a cutting element that has a tendency to expand beyond the catheter. Accordingly, claim 26 is allowable over Parins in view of Okada and Tihon taken separately or in combination.

Claims 2-8, 11-14, 16-18, 20, 23-25, and 27-29 are rejected as being obvious over Parins in view of Okada, Tihon, and/or Mueller.

Mueller discloses a catheter with a cutting element and a balloon mounted adjacent to the cutting element. The balloon can be inflated to press the cutting element against tissue to be cut. See Fig. 1.

Mueller, however, fails to cure the deficiency of Parins, Okada, and Tihon, taken separately or in combination to describe or suggest: (1) a cutting element compressible into a reduced diameter when positioned within the compartment and tending to radially expand beyond the catheter wall when positioned near the window or (2) a cutting element having a tendency to expand beyond the catheter wall when positioned near the at least one window. According, claims 2-8, 11-14, 16-18, 20, 23-25, and 27-29 are allowable over Parins in view of Okada, Tihon, and/or Mueller, taken separately or in combination.

Applicant respectfully submits that all claims are condition for allowance. Authorization is given to apply any charges or credits to Deposit Account No. 502923.

Respectfully submitted,

Date: March 23, 2004

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Title: Percutaneous Transmyocardial Revascularization (PTMR) System

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Respectfully submitted,

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